Translation

PCT Application
PCT/JP2002/008212

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-1503-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP02/08212	International filing date (*day/month/year*) 12 August 2002 (12.08.02)	Priority date (*day/month/year*)
International Patent Classification (IPC) or national classification and IPC G01N 33/53, G01N37/00, C12Q 1/68, C12N 15/09, C12M 1/00, G01N 27/30		
Applicant HITACHI HIGH-TECHNOLOGIES CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 12 August 2002 (12.08.02)	Date of completion of this report 06 January 2003 (06.01.2003)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/08212

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-21, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-7,9,10,12-14, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 8,15-20, filed with the letter of 11 December 2002 (11.12.2002)

☒ the drawings:

pages 1-14, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☒ the claims, Nos. 11
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

Whereas the inventions of claims 1-7 concern the quantification of nucleic acids contained in a sample based on multiple nucleic acid probes in which the output exceeds a specified value, the inventions of claims 8-14 are merely inventions concerning a DNA microarray with multiple probes. This examination finds that no single general inventive concept is shared by these two groups of inventions.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. _____

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10, 12-20	YES
	Claims		NO
Inventive step (IS)	Claims	1-10, 12-20	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-10, 12-20	YES
	Claims		NO

2. Citations and explanations

Document 1 [JP 2000-235036 A (Fuji Photo Film Co., Ltd.) August 29, 2000] describes a DNA microarray having multiple nucleic acid probe members and a quantification process using a DNA microarray. It also describes recording on a computer the ratio and length of cDNA bases arrayed on the carrier at each position and the specific values concerning that cDNA such as the amount of fluorescence when a certain number N of cDNA units are contained in a single position on the carrier.

Document 2 [JP 2000-235035] A (Hitachi Software Engineering Co., Ltd.) August 29, 2000] describes a biochip having multiple spots, the determination of the quantity of probes immobilized at each spot, and the measurement of the extent that a sample has been hybridized.

Document 3 [JP 2002-31636 A (Becton Dickinson and Co.) January 31, 2002] describes the detection of the existence of a sample with specific properties by plotting on a graph the optically measured records of biological or chemical samples collected at respective points in time, correcting for an additive background value present in the measured records, and comparing the corrected measured records to a specific threshold value.

Document 4 [JP 2001-321198 A (Fuji Photo Film Co., Ltd.) November 20, 2001] describes the measurement of DNA, etc., by a MOSFET, etc.

Document 5 [JP 2001-299346 A (Hiroyuki Nanami) October 30, 2001 describes performing PCR on a solid phase and quantifying the DNA.

Claims 1-7

None of the above documents describes or suggests a method and device for taking the distribution at each time, performing normalization, and quantifying nucleic acids.

Claims 8-20

None of the above documents describes or suggests a DNA microarray having nucleic acid probes with differing hybridization times or a DNA microarray having multiple probe members with differing nucleic acid probe surface areas.